

TRANSLATION PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference VIV0501PCT	FOR FURTHER ACTION See Form PCT/IPBA416	
International application No. PCT/EP2005/050444	International filing date (day/month/year) 27.01.2005	Priority date (day/month/year) 27.01.2004
International Patent Classification (IPC) or national classification and IPC A61C13/00 A61K6/027 A61C13/083 C04B38/00 C04B41/45 C04B41/49 C04B41/50 C04B35/48 C04B35/488		
Applicant IVOCLAR VIVADENT AG		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 12 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☒ (sent to the applicant and to the International Bureau) a total of 6 sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☒ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒ Box No. I Basis of the report

☐ Box No. II Priority

☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☐ Box No. IV Lack of unity of invention

☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☐ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

☒ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purpose of:
- ☐ international search (Rule 12.3 and 23.1(b))
 - ☐ publication of the international application (Rule 12.4)
 - ☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

- ☐ the international application as originally filed/furnished

- ☒ the description:

pages 1-29 _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

- ☒ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1-39 _____ received by this Authority on 21.10.2005 with telexfax

nos.* _____ received by this Authority on _____

- ☒ the drawings:

sheets 1-4 _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (specify): _____

☐ any table(s) related to sequence listing (specify): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (specify): _____

☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
1. Statement		
Novelty (N)	Claims 2, 3, 5-12, 16, 18, 20, 21, 23, 24, 26-28, 33, 36, 39	YES
	Claims 1, 4, 13-15, 17, 19, 22, 25, 29-32, 34-37	NO
Inventive step (IS)	Claims	YES
	Claims 1-39	NO
Industrial applicability (IA)	Claims 1-39	YES
	Claims	NO
2. Citations and explanations (Rule 70.7)		
Reference is made to the following documents:		
D1: US A 626 392 (KONDO ET AL) 2 December 1986 (1986-12-02)		
D2: WO 2004/032986 A1 (MATHYS ORTHOPAEDIE GMBH) 22 April 2004 (2004-04-22)		
D3: US-A-5 447 967 (TYSZBLAT ET AL) 5 September 1995 (1995-09-05)		
D4: US 2002/162482 A1 (GIORDANO RUSSELL A) 7 November 2002 (2002-11-07)		
D5: WO 99/52467 A (LEONHARDT, DIRK) 21 October 1999 (1999-10-21)		
D6: WO 88/02742 A (WASHINGTON RESEARCH FOUNDATION) 21 April 1988 (1988-04-21)		
D7: US-A-4 925 492 (KELKAR ET AL) 15 May 1990 (1990-05-15)		
D8: EP-A-0 328 316 (SHINAGAWA SHIRORENGA KABUSHIKI KAISHA) 16 August 1989 (1989-08-16)		
D9: INWANG I B ET AL: "ZIRCONIA INFILTRATION TOUGHENING OF NA-BETA-ALUMINA" JOURNAL OF MATERIALS SCIENCE, CHAPMAN AND HALL LTD., LONDON, GB, Vol. 36, No. 7, 1 April 2001 (2001-04-01), pages 1823-1832, XP001048276 ISSN: 0022-2461		

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
D10:	YUNG-JEN LIN ET AL: "Cyclic infiltration of porous zirconia preforms with a liquid solution of mullite precursor" JOURNAL OF THE AMERICAN CERAMIC SOCIETY, AMERICAN CERAMIC SOC USA, Vol. 84, No. 1, January 2001 (2001-01), pages 71-78, XP002331268 ISSN: 0002-7820
D11:	SKALA ET AL: "Synthesis and properties of mullite/zirconia toughened alumina (ZTA) composites" INTERNATIONAL CERAMIC MONOGRAPHS. PROCEEDINGS OF THE INTERNATIONAL CERAMICS CONFERENCE, AUSTICERAM 94, 1994, Vol. 1, pages 161-166, XP008048279
D12:	DURAN P ET AL: "Nanostructured and near defect-free ceramics by low-temperature pressureless sintering of nanosized Y-TZP powders" JOURNAL OF MATERIALS SCIENCE CHAPMAN & HALL UK, Vol. 32, No. 17, 1 September 1997 (1997-09-01), pages 4507-4512, XP002331269 ISSN: 0022-2461.
1.	Novelty (PCT Article 33(2))
	Interpretation of the claims
a.	The phrase "for use in dentistry" refers to the use of a product and does not define any technical features of the product.
	The word "for" should be interpreted to mean "suitable for use". It is not essential for the prior art to mention that a product is used for a particular purpose. It suffices if it would be possible to use a product for a given purpose (see the PCT Guidelines, chapter 4.8).

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<p>b. All the features preceded by "preferably" or "in particular" are optional.</p> <p>c. It can be assumed that in the case of an infiltration/coating the thickness of the layer of infiltrate normally ranges from 5 to 20 %.</p> <p>d. Claim 25: many materials are at least somewhat translucent. It is not necessary for the prior art to mention that the core is translucent in order for it to be prejudicial to novelty. It is sufficient for the prior art to disclose a core made of a material which is known normally to be translucent.</p> <p>e. As defined in claim 25 the inner area is not necessarily intended to be infiltrated. According to the definition given in claim 25, the applied layer is not necessarily intended to partly infiltrate the core. Claim 25 therefore claims a coating of a translucent material such as aluminium oxide or zirconium oxide.</p> <p>f. Claim 25: material properties such as biaxial strength and fracture toughness are the results of a particular material composition. Properties of this kind cannot establish a difference over the prior art; only the composition as a result of which the properties arise could do so.</p> <p>g. Claim 37: the feature of claim 37 remains entirely undefined since the hot isostatic pressing of a ceramic material does not always result in the same translucence. If the applicant wishes to define a particular</p>		

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	<p>translucence he should supply quantitative values. A qualitative definition of the kind given in claim 37 has no restrictive effect.</p>
	<p>Objections with regard to novelty</p>
	<p>h. Document D11 refers to a mixture of 15 % by weight zirconium oxide and 85 % by weight aluminium oxide. This mixture is pressed and presintered at 1000 °C. After presintering the porous moulded body is infiltrated at room temperature with a solution of tetraethylorthosilicate (see page 162). The infiltration can last as little as 5 minutes (see table 1, example Z2). After sintering at 1550 °C in ambient air and at atmospheric pressure, the infiltration phase forms a mullite phase (see page 162). Table 1 discloses the density of the presintered product. All the products have a density of more than 99.5% , since a porosity of less than 0.5 % corresponds to a density of more than 99.5 %. Moreover, figure 4 also discloses the fracture toughness of the sintered products, which in all cases is greater than 6.5 Mpa m^{1/2}. Biaxial strength is not mentioned, but it can be assumed that it is likely to be greater than 800 Mpa (see also point 4f of the present report). It can further be assumed that this product can be used in dentistry, as is the case with almost all aluminium oxide and zirconium oxide ceramic products.</p>
	<p>Owing to the disclosure of document D11, the present application does not meet the requirements of PCT Article 33(1) because the subject matter of claims 1, 4, 13-15, 17, 19, 22, 25, 29-32 and 34-37 is not novel within the</p>

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<p>meaning of PCT Article 33(2).</p> <p>2. Inventive step (PCT Article 33(3))</p> <p>a. Document D4 discloses a pressed moulded oxide part, which is sintered at 400-1200°C into a porous ceramic material used as a dental structure. During the moulding of the moulded part a polyvinyl binder is used. The porous ceramic material is infiltrated with a silane (see paragraphs 27 and 28). The infiltration takes place at a pressure of less than 4×10^{-2} Torr (that is to say, 0.056 mbar, see paragraph 33). The porous ceramic material can also be infiltrated with molten glass (see paragraph 34). The matrix contains, for example, zirconium oxide or aluminium oxide (see paragraph 35). The surface can then be processed in a material-removing manner (see paragraph 38).</p> <p>Document D4 therefore clearly states that the use of ethylenic waxing agents as binders for dental ceramics is known, as is the concept of infiltrating at less than 40 mbar and obtaining a vitreous phase after the infiltration. Owing to the content of document D4 the present application does not meet the requirements of PCT Article 33(1), since the subject matter of claims 2, 3, 5, 6, 20, 23, 24, 33, 38 and 39 is not inventive within the meaning of PCT Article 33(3).</p> <p>b. Document D6 discloses an aluminium oxide powder which is mixed with an ethylenic waxing agent. After pressing the green bodies are presintered at 1100°C. After presintering the moulded body is processed in a</p>		

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	<p>material-removing manner (see example 1). The porous moulded body is infiltrated with zirconium acetate sol at a pressure of 1.5×10^{-2} Torr and then densely sintered at 1200°C or 1700°C (see example 2). A zirconium alkoxide, zirconium polymer or a zirconium salt can also be used for the infiltration. The zirconium oxide can be stabilized with yttrium oxide (see page 6, lines 1-34). After sintering the composite material is processed in a material-removing manner (see example 6).</p> <p>Document D6 further clearly states that the use of ethylenic waxing agents as binders for dental ceramics is known, as is their infiltration at less than 40 mbar. Document D6 further suggests the possibility of processing the moulded body in a material-removing manner after the presintering or final sintering. Owing to the content of document D6, the present application does not meet the requirements of PCT Article 33(1) because the subject matter of claims 2, 3, 5, 6, 16, 20, 23 and 24 is not inventive within the meaning of PCT Article 33(3).</p> <p>c. Document D1 discloses a zirconium powder which is mixed with 3 mol % yttrium oxide and a binder, pressed into a moulded part and presintered at 1200 °C to yield a porous moulded body (examples 1 and 3). The porous moulded body is saturated with a calcium phosphate (example 1) or calcium hydroxide (example 3) solution. To speed up the infiltration the moulded part is sintered at 1550 °C. Thereafter, an apatite layer is applied to the surface and subjected to heat treatment. Examples 2 and 4 disclose similar methods using aluminium oxide moulded parts. After sintering a material-removing process takes</p>	

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p data-bbox="332 289 1268 323">INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY</p> <p data-bbox="971 268 1268 323">International application No. PCT/EP2005/050444</p> <p data-bbox="302 384 1211 453">place, in the sense that the moulded part is subjected to scratching.</p> <p data-bbox="297 520 1211 856">Document D1 points out, <i>inter alia</i>, that the application of a further material to the surface of a composite material is known, as is the use of yttrium-doped zirconium oxide. Owing to the content of document D6, the present application does not meet the requirements of PCT Article 33(1) because the subject matter of claims 2, 5, 6, 18, 20, 21, 23, 24 and 26-28 is not inventive within the meaning of PCT Article 33(3).</p> <p data-bbox="297 919 1206 1260">d. It is not clear with any of claims 7-12 what the unexpected and advantageous technical effect associated with any specific claim might be. In order to be inventive, it should be clear what unexpected advantages a claim might have over the closest prior art. At present this question has not been answered by any of the above claims. Consequently, these claims cannot be considered to involve an inventive step.</p> <p data-bbox="297 1323 1141 1392">e. Similar objections with regard to inventive step arise from documents D2, D5, D7, D8, D9 and D10.</p>

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Disclosure (PCT Article 5)

In the description the applicant has disclosed only yttrium-doped zirconium oxide ceramic compositions as crystalline oxide ceramic phase for the core, and has not credibly demonstrated that the desired effect can also be obtained with a different phase in the core.

Consequently, independent claims 1 and 25 do not satisfy the requirements of PCT Article 5.

2. Clarity (PCT Article 6)

a. The applicant has added the original claims 28 and 36 to the new product claim 25. The features of the original claim 28 refer to the state of the composite material prior to sintering, while the features of the original claim 36 refer to the state after sintering. Consequently, these features are not present at the same time, and hence it is not clear whether the product claimed in claim 25 is the product before or after sintering.

If the applicant wishes to describe a product whose features are not the same at a given moment he can do so only using a so-called "product by process claim", that is to say, a product claim into which method steps are incorporated, it being clear what feature the product has at what point in time. The features of the product at any stage preceding that of end-product, however, are relevant only insofar as they have a defined effect on

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the end product. However, claim 25 in its present form presents a product that has neither existed, nor can ever exist.

The claims dependent on claim 25 likewise contain features which refer to both the unsintered and the sintered product and are described as if they are all features of the same product. Consequently, the claims dependent on claim 25 are likewise unclear.

b. It is not clear what is meant by "excess" in claims 20 and 21. Consequently, these claims are unclear.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Bôx I

Basis of the report**1. Amendments submitted (PCT Article 34(2)(b))**

a. The applicant has added the phrase "the penetration of the infiltrate into the oxide ceramic body is carried out for an infiltration period of less than 10 minutes" to claim 1, referring to page 11, lines 2-4, and page 17, line 13. Although these references are correct, it should be added that on page 11, lines 2-4, of the disclosure, the infiltration period is stated in combination with the use of a vacuum. Consequently, the above addition is contrary to PCT Article 34(2)(b) and permitted only if the use of a vacuum is also added.

b. The applicant has added the original claim 36 to claim 1, and in doing so has omitted the phrase "measured using the indenter method". Fracture toughness, however, was disclosed only in combination with this definition. Consequently, the omission of the above phrase is contrary to PCT Article 34(2)(b).